510(K) SUMMARY: A.I.M. KNOTLESS MENISCAL REPAIR DEVICE

Submission Date: December 11, 2013

JUN 10 2014

Submitter Information:

Company: Anchor Innovation Medical (A.I.M.)
5410 Edson Lane
Suite 308
Rockville, MD 20852

Contact Person: Cary Stalnecker
Chief Executive Officer

Correspondent Information:

Karen M. Becker, Ph.D.
5410 Edson Lane, Suite 308
Rockville, MD 20852

Phone: 301-770-7871
Fax: 301-770-7875
Email: kbecker@anivmed.com

Device Information:

Trade Name: A.I.M. Knotless Meniscal Repair Device

Regulation Name: Suture, non-degradable

Classification: 21 CFR 878.5000

Product Codes: GAT

Device Class: Class II

Predicate Devices: Smith & Nephew, ULTRA FAST-FIX AND ULTRA FAST-FIX AB MENISCAL REPAIR SYSTEMS (K072322)

Intended Use: The A.I.M. Knotless Meniscal Repair Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repair, including the repair of meniscal tears.

Device Description:

The A.I.M. Knotless Meniscal Repair Device is comprised of two implants pre-threaded with commercially available Ultra High Molecular Weight Polyethylene, USP Size 0 suture pre-loaded into a needle delivery device that will allow the surgeon to repair soft tissue, including a meniscal repair. The needle tip may be available straight, curved, and/or reverse-curved.

Substantial Equivalence Summary:

The A.I.M. Knotless Meniscal Repair Device is substantially equivalent to the cited predicate, Smith & Nephew's Ultra Fast-Fix and Ultra Fast-Fix AB Meniscal Repair Systems (K072322), having the same, or similar, intended use, indications for use, and fundamental scientific technology.

The A. I.M. Knotless Meniscal Repair Device employs a different method for deploying the implants, and for tensioning and locking the suture. These differences do not raise new questions of safety or effectiveness.

Performance Testing:

Bench testing was conducted to confirm that the A.I.M. Knotless Meniscal Repair Device performs as well or better than the predicate on pull-out performance and cyclic loading.

Safety Testing:

The A.I.M. Knotless Meniscal Repair Device was determined to be biocompatible based on the component materials, conformity with recognized standards, and testing consistent with the requirements of ISO 10993. Sterilization and packaging validation are consistent with product labeling.

Conclusion:

Based on the similarity in intended use, materials, and fundamental scientific technology, performance testing and safety testing, the A.I.M. Knotless Meniscal Repair Device is as safe and effective, and performs as well or better than, the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

Anchor Innovation Medical
% Karen M. Becker, Ph.D.
5410 Edson Lane, Suite 308
Rockville, Maryland 20852

Re: K133770
Trade/Device Name: A.I.M. Knotless Meniscal Repair Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: May 20, 2014
Received: May 21, 2014

Dear Dr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133770

Device Name: A.I.M. Knotless Meniscal Repair Device

Indications for Use:

The A.I.M. Knotless Meniscal Repair Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repair, including the repair of meniscal tears.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133770